## 薬生食監発0711第1号

## 平成30年7月11日

## 各検疫所長殿

## 医薬・生活衛生局食品監視安全課長

## (公 印 省 略)

米国から輸入されるめん羊及び山羊の肉等の取扱いについて

標記については、「BSE発生国等から輸入されるめん羊・山羊の肉等の取扱いについて」(平成16年2月27日付け食安監発第0227003号(最終改正:平成29年3月3日付け生食監発0303第1号)により取り扱っているところです。

今般、食品安全委員会における「めん羊及び山羊の牛海綿状脳症(BSE)対策の 見直しに係る食品健康影響評価」を踏まえ、米国政府と協議の結果、新たに米国から輸 入されるめん羊及び山羊(以下「めん羊等」という。)の肉等に関する対日輸出プログ ラムを別添1のとおり定めました。

つきましては、本日以降、下記のとおり取り扱うこととしますので、その運用に遺 漏のないようお願いします。

### 記

1 対象品目

米国農務省から認定された対日輸出認定施設においてとさつ、解体、分割、細切又 は製造された、めん羊等の肉、臓器及びこれらを原材料とする食品であって、米国農 務省が発行する衛生証明書が添付されているものとすること。

上記以外の米国の施設においてとさつ、解体、分割、細切又は製造されためん羊 等の肉、臓器及びこれらを原材料とする食品及び添加物のうち、食品衛生法(昭和2 2年法律第233号。以下「法」という。)第9条第2項に基づき衛生証明書を要する ものについてはこれを受け入れないこととし、要しないものについては輸入しない よう指導すること。

なお、対日輸出認定施設のリストについては、別途通知する予定であること。

## 2 衛生証明書

- (1)米国農務省が発行する法第9条第2項に基づく衛生証明書については、別添2の 1のとおりであるので、食品衛生法施行規則(昭和23年厚生省令第23号)第9条に 規定された事項のほか、記の1に示した施設であること及び対日輸出プログラムに 適合している旨(fulfilled the requirements of the USDA EV QSA Program for ovine and caprine meat exported to Japan)等について確認すること。
- (2)食肉製品以外のめん羊等の肉及び臓器を原材料とする食品についても、別添2の 1に示す米国農務省が発行する衛生証明書が添付されることから、(1)の内容を 確認すること。
- (3) 別添2の2の様式が添付された場合にあっては、記載されている処理施設が米国 農務省から認定された対日輸出認定施設であることを確認すること。
- (4)米国以外のBSE発生国又は地域のうち、食品健康影響評価の結果に基づき安全性が確保されると認められ、かつ、輸入条件を定めた国又は地域においてと畜検査が行われためん羊等の肉若しくは臓器については、と畜検査を行った国又は地域の政府機関が対日輸出条件に基づき認定した対日輸出認定施設で処理された肉若しくは臓器であること等必要な要件について確認すること。
- 3 措置
- (1) めん羊等の肉、臓器及びこれらを原材料とする食肉製品

検疫所における検査及び調査の結果、BSE発生国又は発生地域のめん羊等の1 2か月齢超の頭部(扁桃を含み、舌、頬肉及び皮を除く。)及び脊髄並びに全月齢 の脾臓及び回腸の混入と判定された場合には、当該ロットを法第9条第2項に違反 するものとして取り扱うこと。

(2) 食肉製品以外のめん羊等の肉及び臓器を原材料とする食品

検疫所における検査及び調査の結果、BSE発生国又は発生地域のめん羊等の1 2か月齢超の頭部(扁桃を含み、舌、頬肉及び皮を除く。)及び脊髄並びに全月齢 の脾臓及び回腸の混入と判定された場合、若しくは、米国農務省が発行する衛生証 明書が添付されていない場合には、貨物保留の上、検疫所業務管理室を通じて当課 まで連絡すること。

# Requirements for Meat and Meat Food Products Derived from Ovine and Caprine Animals to Be Exported to Japan from the United States of America (United States) as Agreed between the Ministry of Health, Labor, and Welfare (MHLW) and the U.S. Department of Agriculture (USDA)

- 1. Definitions
  - a) Meat and meat food products<sup>1</sup> mean all edible parts of ovine and caprine animals and products derived from ovine and caprine animals from such parts of ovine and caprine animals and are produced in a manner that ensures the hygienic removal of prohibited materials, as defined in item 1 (b) of this section.
  - b) Prohibited materials mean head (including tonsils, and excluding tongue, cheek, and skins) and spinal cord of ovine and caprine animals over 12 months of age, and spleen and ileum of ovine and caprine animals of all ages. The ileum is described as the straight, terminal part of the small intestine passing cranially ventral to the cecum to which it is connected by the ileocecal fold and enters the large intestine on the ventral medial surface of the ceccoclic junction.
  - c) **Designated facilities** mean any slaughterhouses, meat cutting facilities, meat processing facilities, and storage facilities that operate under USDA inspection and handle eligible materials as defined in items 1(a) and 1(b) of this section.
  - d) The United States means the 50 states, the District of Columbia, and Guam.
- 2. Requirements for Designated Facilities
  - a) Any Federally inspected U.S. meat establishment may be certified by USDA as a designated facility eligible to export to Japan. The designated facility will be certified as eligible upon the U.S. government notification to the Japanese government of the designated facility's name, address, and establishment number as listed in the USDA's Food Safety and Inspection Service (FSIS) Meat and Poultry Inspection (MPI) Directory.
  - b) Only designated facilities that have implemented an AMS-approved QAD Procedure 1031A Export Verification (EV) Program for Japan, which meets the specified product requirements for Japan, will be listed on the Official Listing of Eligible Suppliers to the USDA Ovine and Caprine EV Program. The QAD Procedure 1031A EV Program for Japan ensures that requirements are supported by a documented quality management system.

<sup>&</sup>lt;sup>1</sup> As defined in the U.S. Federal Meat Inspection Act (21 U.S.C. Sec 601 et seq. (2012)).

## 3. Requirements for Ovine and Caprine Meat and Meat Food Products

Ovine and caprine meat and meat food products for export from the United States to Japan must meet the following requirements:

- a) The exported meat and meat food products derived from ovine and caprine animals to Japan must be derived from either:
  - (A) Animals that were born and raised only in the United States, or from animals legally imported into the United States from a country recognized by the Japanese animal health authorities as:
    - The third free countries for cloven-hoofed animals and meat as authorized by Japan. A link to the current list of these eligible countries will be available on FSIS's Export Library website;
    - (ii) The eligible BSE-affected countries as identified by Japan. A link to the current list of these eligible countries will be available on FSIS's Export Library website; Or
  - (B) Meat and meat food products legally imported into the United States from a designated facility in a country recognized by Japan as eligible to export ovine and/or caprine meat and meat food products to Japan and shipped directly to the U.S. ports of entry. If transported through countries other than the eligible third-free countries or eligible BSE-affected countries, as identified on the current lists available on FSIS's website, the imported meat and meat food products must be transported in an officially sealed container. Once inspected and passed by FSIS, the shipment of imported meat and meat food products must transfer directly to the designated facility in the United States.
- b) For the purpose of age determination for the removal of prohibited materials, the age of ovine and caprine animals at the time of slaughter was determined by the establishment and verified as acceptable by USDA's AMS through its oversight of the QAD Procedure 1031A EV Program for Japan.
- c) The ovine and caprine meat and meat food products were produced and handled in a manner to ensure segregation from prohibited materials in accordance with the QAD Procedure 1031A EV Program for Japan.
- d) Ovine and caprine meat and meat food products that are eligible for export to Japan as defined in item 1(a) of these requirements and listed on the FSIS website must be processed in accordance with FSIS regulations and the QAD Procedure 1031A EV Program for Japan.
- 4. Audits and Monitoring
  - a) The Japanese government may conduct routine onsite audits of the U.S. inspection system through representative samples of eligible designated facilities that export ovine and caprine meat and meat food products to Japan to verify compliance with the relevant requirements detailed in this

document and U.S. regulations. In the event that a non-compliance with the requirements detailed in this document is found as a result of the onsite audit, the Japanese government will inform the U.S. government onsite of the finding. FSIS would issue a Non-compliance Record (NR) for findings related to U.S. regulations and AMS would cite the non-conformance for findings related to the QAD Procedure 1031A EV Program for Japan. Non-compliant and/or non-conformant product would be controlled immediately. If the process that resulted in the non-compliant and/or non-conformant product is ongoing, USDA would immediately stop the process until it determines the appropriate corrective and preventative measures have been taken. Only when USDA determines that corrective actions are adequate will it permit production to resume.

- b) USDA must confirm through ordinary monitoring or periodic audit that designated facilities are fulfilling required conditions of section 3 of this document. If during ordinary monitoring or periodic audit of a designated facility USDA identifies a non-compliance and/or non-conformance with conditions of section 3 of this document, USDA will stop certifying ovine and caprine meat and meat food products for Japan produced at the non-compliant and/or non-conformant facility for export to Japan. USDA may revoke the designation of the non-compliant and/or non-conformant facility and must inform the Japanese government of the name, address, and establishment number of that facility. After verifying that acceptable corrective actions have been taken, USDA may re-designate the revoked facility.
- c) USDA will verify that the revoked designated facility has determined and implemented appropriate corrective and preventative measures to address the non-compliances and/or non-conformances.
   USDA will inform MHLW of the corrective and preventative measures the designated facility has taken and of the date the suspension is lifted.
- 5. Export Certificate
  - a) Ovine and caprine meat and meat food products qualify for import quarantine inspection by the Japanese government if accompanied by the Export Certificate of Wholesomeness, the Certificate for Export to Japan, and the Letterhead Certificate for the Export of Ovine and Caprine Meat and Meat Products to Japan issued by authorized personnel under the U.S. Federal Meat Inspection Act, which include the following information, in English, to be submitted to the quarantine authority of the Japanese government, as required by the Food Safety Act of Japan:
    - 1) Name, address, and establishment number of each meat establishment where a relevant procedure, such as slaughtering or processing, occurred;
    - 2) Slaughtering and/or processing date range (dd/mm/yy-dd/mm/yy);
    - Date, authorities' name, and place of issue of the inspection certificate, and name and title of signer; and
    - 4) Required condition in item 5(b) below.

b) Eligible products produced by eligible designated facilities and identified as meeting the requirements of the QAD Procedure 1031A EV Program for Japan must receive an FSIS export certificate with a statement indicating that the eligible products fulfilled all of the requirements of the QAD Procedure 1031A EV Program for Japan. According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0153. The time required to complete this information collection is estimated to average 25 minutes per response, including the time for reviewing instruction, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE Meat and Poultry Export Certificate of Wholesomeness		A knowingly false entry or false alteration of any entry on this certificate may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both (18 U.S.C.1001). Additional penalties exist under the Federal Meat Inspection Act [21 U.S.C. 611(b) (1), (2); and (5), 21 U.S.C. 461] for an unauthorized or false alteration or misuse of this certificate.				
1. COUNTRY OF DESTINATION	2. ISO CODE	5. CERTIFICATE NUMBER		6. CERTIFICATE TYPE		
					ORIGINAL	-
		MPM-			REPLACE	MENT
3. CONSIGNOR/EXPORTER (Applicant's name and address)		PRODUCT EXPORTED FROM:				
		7. EXPORT EST. NO. (Name and address)				
4. CONSIGNEE/IMPORTER (Name and address)		-				
		8. TOTAL N	NET WEIGHT		9. TOTAL NO. OF F	PACKAGES
10. DESCRIPTION OF PRODUCT (Name of product)	11. NET WEIGHT OF LOT <sup>1</sup>	12. SPECIES	13. NUMBER OF PACKAGES IN LOT <sup>1</sup>	14. TYPE OF PACKAGES IN LOT	15. SHIPPING/ IDENTIFICATION MARKS <sup>1</sup>	16. EST. NO. ON PRODUCT
		$\bigcirc$		US65		
		$\mathbf{K}$	to be			
			Å.			
	$\sim$					
<sup>1</sup> As stated by applicant or contractor		NO				
17. REMARKS	This san	X				

18. I CERTIFY that the meat, meat food product or meat byproduct specified hereon is from animals that received both antemortem and postmortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and regulations of the Department and is sound and wholesome.

19. I CERTIFY that the poultry, poultry products or poultry food products specified above came from birds that were officially given an antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture and are wholesome and fit for human consumption.

NOT VALID UNLESS SIGNED BY A CERTIFYING OFFICIAL OF MEAT AND POULTRY INSPECTION PROGRAM

By order of the Secretary of Agriculture



20. CERTIFYING OFFICIAL'S NAME AND TITLE

21. DATE SIGNED (MM/DD/YYYY)

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture. CORRESPONDING EXPORT CERTIFICATE



IDENTIFICATION OF PRODUCT					
1. SPECIES	2. DESCRIPTION OF ITEM				
3. NUMBER OF PACKAGES OR PIECES	4. NET WEIGHT				
ORIGIN OF	PRODUCT				
5. NAME, ADDRESS AND ESTABLISMENT NUMBER OF SLAUGHTER PLANT	6. NAME, ADDRESS AND ESTABLISHMENT (For plants preparing cuts or packaging byp				
7. DATE (Month & Year) OF MANUFACTURE (Or packing date)	<ol> <li>NAME &amp; ADDRESS OF MANUFACTURING (Processed products only)</li> </ol>	9 PLANT			
INSP	ECTION				
9. DATE (Month & Year) OF SLAUGHTER AND INSPECTION	10. NAME OF AGENCY OR NAME & TITLE ( SLAUGHTER INSPECTION (Veterinarian (If product fresh frozen)				
11. NAME AND ADDRESS OF CONSIGNOR	12. NAME AND ADDRESS OF CONSIGNEE				
The meat and/or meat products described herein were processed regulations of the United States. The laws and regulations of the inspection laws of Japan.	I d under sanitary conditions in accordance with late United States have been deemed to be equival	ws and ent to the			
13. SIGNATURE OF OFFICIAL	14. TITLE OF OFFICIAL	15. DATE			



United States Department of Agriculture

Food Safety and Inspection Service Washington, D.C. 20250

# Letterhead Certificate for the Export of Ovine and Caprine Meat and Meat Products to Japan

Date Issued:\_\_\_\_\_ Certificate Number: \_\_\_\_\_

The ovine and caprine meat and meat products exported to Japan were derived from:

 a. slaughtered animals that were born and raised only in the USA; or
 b. animals legally imported from a country recognized by the Japanese animal health authorities as eligible in accordance with the requirements of the USDA Export
 Verification Quality System Assessment (EV QSA) Program for ovine and caprine meat exported to Japan; or

c. ovine and caprine meat and meat products that were legally imported from a country recognized by the Japanese animal health authorities as eligible in accordance with the requirements of the USDA EV QSA Program for ovine and caprine meat exported to Japan.

- 2. The slaughtered animals were not suspect or confirmed BSE cases.
- 3. The slaughtered animals were not suspect or confirmed Scrapie cases.
- 4. The ovine and caprine meat and meat products exported to Japan were produced and/or handled in eligible meat establishments in the United States that fulfilled the requirements of the USDA EV QSA Program for ovine and caprine meat exported to Japan.
- 5. The ovine and caprine meat and meat products were handled in a manner to prevent contamination with any causative agents of animal infectious diseases.

\_\_\_\_\_

Signature of FSIS Inspection Official:

Printed Name:

Title/Professional Degree:

Certificate Edition: 03/28/2018 FSIS Form 2630-9 (6/86)

EQUALOPPORTUNITY IN EMPLOYMENT AND SERVICES



United States Department of Agriculture Food Safety and Inspection Service Washington, D.C 20250

## Letterhead Certificate Establishment Continuation Sheet for FSIS Form 9290-1 Certificate for Export to Japan

(For use as needed by the final processor of fresh/frozen and processed beef, ovine, caprine, other meat or poultry products exported to Japan)

Date Issued:	Certificate Number:				
Box 5. Name, Address and Establishment Number of Slaughter Plant(s):					
1.					
2.					
3.					
4.					
5.					

Box 6. Name, Address and Establishment Number (For plants preparing cuts or packaging byproducts).

1.	SAM	DI	
2.			
3.			
4.			
5.			

#### Signature of FSIS Inspection Official:

Printed Name:

Title of Official: